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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,679

10/17/2005

Peter Tass

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535 7590 04/14/2010

KF ROSS PC
5683 RIVERDALE AVENUE
SUITE 203 BOX 900
BRONX, NY 10471-0900

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

04/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EMAIL@KFRPC.COM
ereyes@kfrpc.com

DETAILED ACTION

Claim Objections

Claims 85-89 are objected to because of the following informalities:

Claims 85-89 refer to “the method” of claim 78. The method claim is claim 84 and not 78. Since these claims are the same as the other dependent claims that refer to the apparatus, claims 85-89 have been interpreted as depending from claim 84 and should be amended accordingly. In addition, there are two claims 88. The examiner has interpreted the second claim as 89 and the claim should be amended accordingly. Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 88-94 must be renumbered to 89-95 (and will be referred to as such in this action).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 78-83 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter of claiming a connection to the body or step of implanting the electrodes. Apparatus claims can not claim a connection to the body. It is suggested to state "adapted to be implanted" or "for implanting".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90 and 91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter not in the original disclosure is the use of the electrodes arrayed "symmetrically" in combination with the other elements/steps in the claim(s). The original disclosure used "substantially" symmetrical in paragraph 84 and therefore the use of "symmetrical" without "substantially" is a different range.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 90 and 91, "arrayed symmetrically" and "implanted symmetrically" are vague since there is no claimed reference point and it is unknown what they are symmetric to.

In claims 92 and 93, the claims state that each subpopulation is fed with a different burst at different times with respect to each of the other populations but also that two electrodes are

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fed simultaneously. It is unclear how the electrodes can be fed at different times but simultaneously. These claims could not be further examined in view of art due to the conflicting claim limitations.

In claim 94, “a stochastic or deterministic algorithm” is inferentially included and it is unclear if the applicant is positively or functionally reciting the algorithms.

In claim 95, “implanted in respective subpopulations” is vague and in the passive voice. It is unclear if this is a positive recitation of implanting the electrodes and it is suggested to use active voice to claim a positive method step of implanting the electrodes in the subpopulations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 78-81, 84-87, 90 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al (6459936). Fischell applies offset stimulation signals to neuron populations through implanting electrodes in the subpopulation (e.g. figure 1) to stop/prevent/reset/reverse/desynchronize the populations as an epilepsy treatment therapy (e.g. see col. 15, col. 22-24, etc) using stimulation that can be from 0.1 Hz to 1000 Hz for 1 millisecond to 30 minutes and can use different frequencies for each electrode (e.g. col. 3, line 10). Fischell also states that the stimulations from the different electrodes will be applied with a relative delay with respect to each other and therefor has the bursts fed to each subpopulation

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time shifted to other bursts (e.g. col. 8, line 38, col. 22, line 31). For claims 90 and 91, Fischell meets this claim limitation since he is capable of being symmetrical and is symmetrical to a midpoint between the electrodes.

Claims 78-81, 84-87, 90, 91, 94, and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Pless (7174213). Pless applies offset stimulation signals to neuron populations and subpopulations to stop/prevent/reset/reverse/desynchronize the populations as an epilepsy treatment therapy (e.g. see col. 18, using different electrodes to deliver different pulse to pulse timing, figures 3, 4, 21, 22, etc and see col. 19 of using multiple electrodes spaced apart for one large focus7) using stimulation that can be from around 0.5 Hz to 500 Hz for 0.05 to 60 minutes and shows in figure 3 a set of 4 pulses in a burst being delivered. NOTE, different pulse to pulse timings (i.e. different frequencies) will necessarily result in pulses being offset from one another. For example, electrodes firing at 3, 5, and 7 Hz will provide different offsets. For claims 90 and 91, Pless meets this claim limitation since he is capable of being symmetrical and is symmetrical to a midpoint between the electrodes. Pless also states (e.g. col. 6, lines 25-45) that the electrodes used can be varied using a preprogrammed sequence or based upon the characteristic of the epileptogenesis waveform and therefore uses a "deterministic algorithm" (i.e. an algorithm that has an outcome that can be predicted, has an outcome that is casually determined by preceding events, and/or has an outcome in which no randomness is involved in the development of future states)

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 81-83, 87-89, 94 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell or Pless.

Fischell or Pless discloses the claimed invention and setting different offset parameters for particular patient based on the patient's neural disease (e.g. epileptic focus) during testing of the patient (e.g. col. 24 in Fischell, col. 10, 11, in Pless) except for the exact pulse parameters of all having the same time duration, being identical, or the offsets being identical and using a deterministic algorithm for varying subsets of electrodes for stimulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation systems and methods as taught by Fischell or Pless with the exact pulse parameters of all having the same time duration, being identical, or the offsets being identical, and using a deterministic algorithm for varying subsets of electrodes for stimulation since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05). In addition, since Fischell or Pless both

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disclose trying different electrical stimulation parameters to determine the appropriate stimulation for a particular patient and varying the electrodes used, it would have been obvious to one having ordinary skill in the art to try different stimulation parameters, such as the exact pulse parameters of all having the same time duration, being identical, or the offsets being identical, and using a deterministic algorithm for varying subsets of electrodes for stimulation to provide the predictable results of an effective stimulation pattern and therapy to suit a particular patient's needs and disease and to use a deterministic model to vary the electrode subset to provide the predictable results of producing the same output for a given starting condition to continually use the same effective electrode set for a known condition.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The applicant argues that Fischell and Pless do not place multiple electrodes within the epileptic focus. This argument is not persuasive for the apparatus claims since Fischell and Pless are capable of placing electrodes in the same large neuron population since they are capable of being placed throughout the brain. Note that the apparatus claims contain "intended/functional use" recitations and can not claim the actual placement of electrodes, just a device capable of placing electrodes. In addition, Pless states that the focus can be through the brain (e.g. col. 19) and the electrodes can be placed accordingly. Both Fischell and Pless do treat seizures of the entire brain, such as a tonic-clonic seizure/grand mal (the corresponding large population being the entire brain). Finally, the method claims do not claim placing the electrodes within an epileptic focus but only claim

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placing the electrodes within a "a large neuron population" (e.g. the brain) which Fischell and Pless accomplish.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
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